

Decision number: TPE-D-2114312117-63-01/F

Helsinki, 05 January 2016

**DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006****For bisdecanoyl peroxide, EC No 212-092-1 (CAS No 762-12-9), registration number:** [REDACTED]**Addressee:** [REDACTED]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

**I. Procedure**

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for bisdecanoyl peroxide, EC No 212-092-1 (CAS No 762-12-9), submitted by [REDACTED] (Registrant).

- Daphnia magna Reproduction Test (OECD 211).

This decision is based on the registration as submitted with submission number [REDACTED], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 27 May 2015, i.e. 30 calendar days after the end of the commenting period.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 30 April 2013.

On 20 March 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 21 April 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting to have the deadline for performing the test and for updating the dossier extended to 15 months.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, only the deadline in Section II was amended.

On 3 September 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

## II. Testing required

### A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

### B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **12 April 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

## III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

### A. Tests required pursuant to Article 40(3)

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

#### a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

“Long-term toxicity testing on aquatic invertebrates” is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for a long-term toxicity study on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification: *'In accordance with column 2 of REACH Annex VII, the long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble. The solubility of the substance was determined to be 120 µg/L; as no toxicity was observed during short-term toxicity testing on aquatic organisms it is proposed to perform a long-term aquatic toxicity study on Daphnia according to the OECD 211 guideline.'*

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

ECHA notes that the Registrant has waived the long-term toxicity study on fish with the following justification: *'In accordance with column 2 of REACH Annex VII, the long-term aquatic toxicity studies on (Annex IX, section 9.1.5 & 6) shall be considered if the substance is poorly water soluble. The solubility of the substance was determined to be 120 µg/L; as no toxicity was observed during short-term toxicity testing on aquatic organisms it is proposed to perform a long-term aquatic toxicity study on Daphnia according to the OECD 211 guideline. For these reason, no long-term test on fish is proposed.'*

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive or substantially more sensitive, long-term studies may be required on both fish and *Daphnia*.

ECHA notes that no toxicity was observed up to the water solubility limit for the available short-term tests on aquatic organisms. ECHA also notes that the Registrant has made a read-across for short-term toxicity to fish, the test substance used for that endpoint being dilauroyl peroxide (CAS No 105-74-8, EC No 203-326-3) instead of the registered substance. From the available information, ECHA considers that there is no compelling evidence available in the dossier that fish would be substantially less sensitive than aquatic invertebrates and algae (i.e. by a factor of 10 or more).

In such case, according to the integrated testing strategy presented in Chapter R7b of ECHA *Guidance*, long-term studies on both fish and *Daphnia* may be necessary, but the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study toxicity is observed, then the Registrant will have to conduct a chemical safety assessment (CSA) and to provide an exposure assessment and risk characterisation for the environment in the chemical safety report (CSR) according to Annex I of the REACH Regulation. If no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

#### b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211)

#### Notes for consideration by the Registrant

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

#### IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed test, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the test proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

#### V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at <http://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised<sup>1</sup> by Claudio Carlon, Head of Unit, Evaluation, E2.

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<sup>1</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.